

# EXHIBIT 1

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12 **UNITED STATES DISTRICT COURT**  
13 **CENTRAL DISTRICT OF CALIFORNIA**  
14 **WESTERN DIVISION**

14 CENTOCOR ORTHO BIOTECH, INC.,  
15 Plaintiff,  
16 v.  
17 GENENTECH, INC. AND CITY OF  
18 HOPE,  
19 Defendants.

) Case No. CV 08-03573 MRP (CTx)  
)  
) The Honorable Mariana R. Pfaelzer  
)  
) **DEFENDANTS GENENTECH,**  
) **INC.'S AND CITY OF HOPE'S**  
) **SECOND AMENDED**  
) **COUNTERCLAIMS**  
) **JURY TRIAL DEMANDED**

19 GENENTECH, INC. AND CITY OF  
20 HOPE,  
21 Counter-Plaintiffs  
22 v.

22 CENTOCOR ORTHO BIOTECH, INC.,  
23 Counter-Defendant  
24 AND

25 GLOBAL PHARMACEUTICAL  
26 SUPPLY GROUP, LLC, CENTOCOR  
27 BIOLOGICS, LLC, AND JOM  
28 PHARMACEUTICALS SERVICES,  
INC.,

Third-party Defendants.

## COUNTERCLAIMS

For its Second Amended Counterclaims against Plaintiff and Counter-Defendant Centocor Ortho Biotech, Inc. (“COBI”), and Third-party Defendants Global Pharmaceutical Supply Group, LLC (“GPSG”), Centocor Biologics, LLC (“CBLLC”), and JOM Pharmaceuticals Services, Inc. (“JOM”), Defendants and Counter-Plaintiffs Genentech, Inc. (“Genentech”) and City of Hope state as follows:

1. This is an action for infringement of United States patents. Accordingly, this action arises under the patent laws of the United States of America, 35 U.S.C. § 1 et. seq. and jurisdiction is properly based on Title 35 United States Code, particularly § 271, and title 28 United States Code, particularly § 1338(a).

2. On information and belief, COBI is a corporation organized under the laws of the Commonwealth of Pennsylvania with a principal place of business in Horsham, Pennsylvania. Based on information provided by Plaintiff in this case, COBI was formed in December 2008 when Centocor, Inc. merged with Ortho Biotech Inc.

3. On information and belief, GPSG is a corporation organized under the laws of Pennsylvania with a principal place of business in Horsham.

4. On information and belief, CBLLC is a corporation organized under the laws of Pennsylvania with a principal place of business in Horsham.

5. On information and belief, JOM is a corporation organized under the laws of Delaware with a principal place of business in New Jersey.

6. Genentech is a Delaware corporation with its principal place of business in South San Francisco, California.

7. City of Hope is a California not-for-profit organization with its principal place of business in Duarte, California. City of Hope is a counterclaimant, along with Genentech, on counterclaims 1 and 3 below.

1           8.     This Court has personal jurisdiction over COBI because, among  
2 other reasons, it has availed itself of this Court to sue Genentech and City of Hope.

3           9.     This Court has personal jurisdiction over GPSG because GPSG  
4 has manufactured, imported, and/or distributed products under circumstances in  
5 which it was reasonably foreseeable that such products would be shipped into the  
6 Central District of California for purchase by customers in the Central District of  
7 California.

8           10.    This Court has personal jurisdiction over CBLLC because  
9 CBLLC has manufactured, imported, and/or distributed products under  
10 circumstances in which it was reasonably foreseeable that such products would be  
11 shipped into the Central District of California for purchase by customers in the  
12 Central District of California.

13           11.    This Court has personal jurisdiction over JOM because JOM has  
14 sold, offered for sale, and/or distributed products under circumstances in which it  
15 was reasonably foreseeable that such products would be shipped into the Central  
16 District of California for purchase by customers in the Central District of California.

17           12.    Venue is proper in this district because, among other reasons,  
18 COBI has availed itself of this Court to sue Genentech and City of Hope and  
19 because GPSG, CBLLC, and JOM have manufactured, imported, sold, offered for  
20 sale, and/or distributed products under circumstances in which it was reasonably  
21 foreseeable that such products would be shipped into the Central District of  
22 California for purchase by customers in the Central District of California.

23           13.    On information and belief, ustekinumab (CNTO 1275) is an  
24 antibody that targets the cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23),  
25 naturally occurring proteins that are important in regulating immune responses and  
26 that are thought to be associated with some immune-mediated inflammatory  
27 disorders, including psoriasis.

28

1           14. On information and belief, all Phase III clinical trials believed  
2 necessary to support an application for approval to sell CNTO 1275 in the United  
3 States have been completed.

4           15. On information and belief, Centocor Inc. filed the Biologics  
5 License Application (BLA) for CNTO 1275 and, in February 2008, it was accepted  
6 for review by the U.S. Food and Drug Administration ("FDA") for the treatment of  
7 chronic moderate-to-severe plaque psoriasis in adults.

8           16. On information and belief, COBI has stated that it expects to  
9 obtain regulatory approval to market and sell CNTO 1275 in the United States by  
10 the end of 2009.

11           17. On information and belief, COBI and CBLLC have been  
12 manufacturing CNTO 1275 in the United States.

13           18. On information and belief, COBI and JOM have been making  
14 substantial preparations to market, offer to sell, and sell CNTO 1275 in the United  
15 States upon receipt of regulatory approval to do so.

16           19. COBI has alleged that it has hired and been training key  
17 management, support and sales personnel to market and sell CNTO 1275; has  
18 retained outside consultants and vendors to assist in its marketing and sale of CNTO  
19 1275 in the United States; has retained suppliers and advertising agencies to prepare  
20 for the launch of the product; has prepared promotional materials for the launch of  
21 the product; has initiated planning for medical affairs and pharmacovigilance  
22 activities associated with the marketing of the product; has built supply capacity;  
23 and is completing manufacturing and distribution launch preparations.

24           20. On information and belief, CBLLC, COBI and/or JOM are  
25 stockpiling supplies of CNTO 1275 in anticipation of receipt of regulatory approval  
26 to market and sell CNTO 1275 in the United States.

27           21. On information and belief, JOM has taken possession of at least  
28 some of the CNTO 1275 that has been manufactured to date and is prepared to offer

1 to sell and sell CNTO 1275 upon regulatory approval of the marketing and sale of  
2 CNTO 1275 in the United States.

3 22. On information and belief, golimumab (CNTO 148), now known  
4 by the trade name Simponi, is an anti-TNF-alpha monoclonal antibody being  
5 developed for the potential treatment of rheumatoid arthritis, psoriatic arthritis,  
6 ankylosing spondylitis, ulcerative colitis, and asthma.

7 23. On information and belief, Centocor Inc. submitted a BLA to the  
8 FDA on June 27, 2008 requesting approval of CNTO 148 as a monthly  
9 subcutaneous treatment for adults with active forms of rheumatoid arthritis, psoriatic  
10 arthritis and ankylosing spondylitis.

11 24. On or about April 24, 2009, the FDA approved CNTO 148 for  
12 use by adults with active forms of rheumatoid arthritis, psoriatic arthritis, and  
13 ankylosing spondylitis.

14 25. On information and belief, COBI, GPSG, and JOM have been  
15 making meaningful preparations to market, offer to sell, sell, and import CNTO 148  
16 in the United States upon receipt of regulatory approval to do so, and upon receipt of  
17 this approval have begun offering to sell, selling, and importing this product. On  
18 information and belief, COBI, GPSG, and/or JOM stockpiled supplies of CNTO 148  
19 in anticipation of receipt of regulatory approval to market and sell CNTO 148 in the  
20 United States.

21 26. On information and belief, JOM has taken possession of at least  
22 some of the CNTO 148 that has been manufactured to date and has begun offering  
23 to sell and selling CNTO 148 after receipt of regulatory approval to market and sell  
24 CNTO 148 in the United States.

25 27. On information and belief, GPSG is involved, at a minimum, in  
26 the manufacture and/or importation of Remicade.

27 28. On information and belief, CBLLC is involved in the  
28 manufacture of Remicade.

1           29. On information and belief, JOM offers for sale, sells, and/or  
2 distributes Remicade and CNTO 148. On information and belief, JOM is or will  
3 upon regulatory approval offer for sale, sell, and/or distribute CNTO 1275.

4           30. U.S. Patent No. 6,417,335 (“the ‘335 patent”) generally relates to  
5 a method of purifying proteins, such as antibodies, made through the use of  
6 recombinant DNA techniques. Specifically, the claims of the ‘335 patent relate to  
7 methods of purifying antibodies using cation exchange resin chromatography.

8           31. Genentech and City of Hope believe that their factual  
9 contentions have evidentiary support or will likely have evidentiary support after a  
10 reasonable opportunity for further investigation or discovery.

11                           **FIRST CAUSE OF ACTION**

12                           **WILLFUL INFRINGEMENT OF ‘415 PATENT**

13           32. Genentech and City of Hope incorporate the allegations of  
14 paragraphs 1-31 as if fully set forth herein.

15           33. On December 18, 2001, United States Patent No. 6,331,415 (“the  
16 ‘415 patent”), which is entitled, “Methods of Producing Immunoglobulins, Vectors,  
17 and Transformed Host Cells For Use Therein,” was duly and legally issued. (A true  
18 and correct copy of the ‘415 patent is attached as Exhibit A).

19           34. Genentech and City of Hope are the owners by assignment of the  
20 right, title, and interest in the ‘415 patent.

21           35. On information and belief, by selling and/or offering to sell  
22 Remicade in the United States, JOM is infringing, contributing to the infringement  
23 of, or inducing the infringement of the ‘415 patent, either literally or under the  
24 doctrine of equivalents.

25           36. On information and belief, by making Remicade in the United  
26 States, CBLLC is infringing, contributing to the infringement of, or inducing the  
27 infringement of the ‘415 patent, either literally or under the doctrine of equivalents.  
28

1           37. On information and belief, by making and/or importing  
2 Remicade in(to) the United States, GPSG is infringing, contributing to the  
3 infringement of, or inducing the infringement of the '415 patent, either literally or  
4 under the doctrine of equivalents.

5           38. On information and belief, by making and/or using CNTO 1275  
6 in the United States, COBI, CBLLC, and JOM are infringing, contributing to the  
7 infringement of, or inducing the infringement of the '415 patent, either literally or  
8 under the doctrine of equivalents.

9           39. On information and belief, by offering to sell, selling, and/or  
10 importing CNTO 148 in the United States, COBI, JOM, and/or GPSG are  
11 infringing, contributing to the infringement of, or inducing the infringement of the  
12 '415 patent, either literally or under the doctrine of equivalents.

13           40. COBI's, GPSG's, CBLLC's and JOM's acts of infringement  
14 have caused damage to Genentech and City of Hope, and Genentech and City of  
15 Hope are entitled to recover from COBI, GPSG, CBLLC, and JOM the damages  
16 sustained by Genentech and City of Hope as a result of COBI's, GPSG's, CBLLC's  
17 and JOM's wrongful acts in an amount subject to proof at trial.

18           41. On information and belief, the infringement of the '415 patent  
19 with respect to all of the products is willful and deliberate, entitling Genentech and  
20 City of Hope to increased damages under 35 U.S.C. § 284 and to attorneys' fees and  
21 costs incurred in prosecuting this action under 35 U.S.C. § 285.

22  
23                   **SECOND CAUSE OF ACTION**  
24                   **INFRINGEMENT OF '335 PATENT**

25           42. Genentech incorporates the allegations of paragraphs 1-31 as if  
26 fully set forth herein.  
27  
28



1           43. On July 9, 2002, United States Patent No. 6,417,335, which is  
2 entitled, "Protein Purification," was duly and legally issued. (A true and correct  
3 copy of the '335 patent is attached as Exhibit B).

4           44. Genentech is the owner by assignment of the right, title, and  
5 interest in the '335 patent.

6           45. On information and belief, by making, using, selling, offering to  
7 sell, or importing Remicade into the United States, COBI, GPSG, CBLLC, and/or  
8 JOM are infringing, contributing to the infringement of, or inducing the  
9 infringement of the '335 patent, either literally or under the doctrine of equivalents.

10           46. On information and belief, by importing ReoPro into the United  
11 States, COBI and/or GPSG are infringing, contributing to the infringement of, or  
12 inducing the infringement of the '335 patent, either literally or under the doctrine of  
13 equivalents.

14           47. On information and belief, by importing CNTO 148 into the  
15 United States, COBI, JOM and/or GPSG are infringing, contributing to the  
16 infringement of, or inducing the infringement of the '335 patent, either literally or  
17 under the doctrine of equivalents.

18           48. On information and belief, COBI's, GPSG's, CBLLC's, and/or  
19 JOM's acts of infringement have caused damage to Genentech, and Genentech is  
20 entitled to recover from these entities the damages sustained by Genentech as a  
21 result of their wrongful acts in an amount subject to proof at trial.

22  
23                   **THIRD CAUSE OF ACTION**  
24           **DECLARATORY JUDGMENT OF INFRINGEMENT OF '415 PATENT**

25           49. Genentech and City of Hope incorporate the allegations of  
26 paragraphs 1-31 and 33-34 as if fully set forth herein.

27  
28

1           50. An actual controversy has arisen and now exists between the  
2 parties concerning whether CBLLC, COBI, JOM, and/or GPSG will infringe the  
3 '415 patent in the future.

4           51. On information and belief, by making meaningful preparations to  
5 market, make, use, sell, offer for sale, and/or import CNTO 1275 in the United  
6 States, CBLLC, COBI, and JOM are engaged in activities directed toward  
7 infringement and/or are making meaningful preparation toward activities that will  
8 imminently infringe the '415 patent.

9           52. Genentech and City of Hope seek a declaratory judgment that  
10 CBLLC's, COBI's and JOM's actions in preparation of the marketing, using,  
11 selling, offering for sale, and/or importing of CNTO 1275 will infringe the '415  
12 patent, either literally or under the doctrine of equivalents.

13           53. On information and belief, by submitting a BLA to the FDA  
14 requesting approval of CNTO 148, coordinating the manufacture and stockpiling of  
15 CNTO 148 for sale per approval of such BLA, amongst other activities, COBI,  
16 JOM, and/or GPSG are engaged in activities directed toward infringement and/or  
17 are making meaningful preparation toward activities that will imminently infringe  
18 the '415 patent, if they have not done so already.

19           54. Genentech and City of Hope seek a declaratory judgment that  
20 COBI's, JOM's, and/or GPSG's actions in preparation for the marketing, using,  
21 selling, offering for sale, and/or importing of CNTO 148 will infringe the '415  
22 patent, either literally or under the doctrine of equivalents.

23           55. On information and belief, COBI's, JOM's, and/or GPSG's  
24 activities directed toward infringement have caused damage to Genentech and City  
25 of Hope, and Genentech and City of Hope are entitled to recover from COBI, JOM,  
26 and/or GPSG the damages sustained by Genentech and City of Hope as a result of  
27 COBI's, JOM's, and/or GPSG's wrongful acts in an amount subject to proof at trial.  
28

**FOURTH CAUSE OF ACTION**

**DECLARATORY JUDGMENT OF INFRINGEMENT OF '335 PATENT**

56. Genentech incorporates the allegations of paragraphs 1-31 and 43-44, as if fully set forth herein.

57. An actual controversy has arisen and now exists between the parties concerning whether COBI and JOM will infringe the '335 patent in the near future.

58. On information and belief, by submitting a BLA to the FDA requesting approval of CNTO 148, preparing to manufacture, or manufacturing CNTO 148 for sale per approval of such BLA, amongst other activities, COBI and/or JOM are engaged in activities directed toward infringement and/or are making meaningful preparation toward activities that will imminently infringe the '335 patent.

59. Genentech seeks a declaratory judgment that COBI's and JOM's actions in preparation of the marketing, making, using, selling, offering for sale, and/or importing of CNTO 148 will infringe the '335, patent, either literally or under the doctrine of equivalents.

60. On information and belief, COBI's and JOM's activities directed toward infringement have caused damage to Genentech, and Genentech is entitled to recover from COBI and JOM the damages sustained by Genentech as a result of COBI's and JOM's wrongful acts in an amount subject to proof at trial.

**PRAYER FOR RELIEF**

WHEREFORE, Defendants and Counter-Plaintiffs Genentech, as to all counterclaims, and City of Hope, as to counterclaims one and three, request that judgment be entered in favor of Genentech and City of Hope and against Plaintiff/Counter-Defendant COBI and Third-Party Defendants GPSG, CBLLC, and/or JOM:

1           1.     That COBI, GPSG, CBLLC, and JOM have infringed, have  
2 actively induced others to infringe, and/or have contributed in the infringement of  
3 the asserted patents as set forth above;

4           2.     That COBI, GPSG, CBLLC, and JOM will in the future infringe  
5 the asserted patents as set forth above;

6           3.     That COBI, GPSG, CBLLC, and JOM account for and pay to  
7 Genentech and City of Hope all damages caused by the infringement of the asserted  
8 patents;

9           4.     That insofar as infringement of the '415 patent is concerned, this  
10 case be declared an exceptional case under 35 U.S.C. § 285 and that Genentech and  
11 City of Hope be awarded their attorney fees incurred in this action;

12           5.     For an award of Genentech and City of Hope's costs of this  
13 action, interest on the award, and other charges to the maximum extent permitted;  
14 and

15           6.     For such other future relief as the Court deems just and proper  
16 under the circumstances.

17                   **DEMAND FOR JURY TRIAL**

18           Pursuant to Fed. R. Civ. P. 38, Genentech and City of Hope demand trial by  
19 jury of all issues so triable.

1 Dated: July 1, 2009

Respectfully submitted,

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8 *Attorney for Defendant Genentech, Inc.*

9 Dated: July 1, 2009

Respectfully submitted,

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16 *Attorney for Defendant City of Hope*

**PROOF OF SERVICE**

I, Adam R. Brausa, am employed in the County of Cook, State of Illinois. I am over the age of 18 and not a party to the within action. My business address is 300 N. LaSalle Street, Chicago, Illinois 60654.

On July 1, 2009, I served a true copy of the following documents described as:

**DEFENDANTS GENENTECH, INC.'S AND  
CITY OF HOPE'S SECOND AMENDED COUNTERCLAIMS**

on the interested parties in this action as follows:

☒ **By E-Mail:** I caused to have delivered such documents to the addressees as set forth below:

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Executed July 1, 2009, in Chicago, Illinois.

Adam R. Brausa  
\_\_\_\_\_  
Print Name

/s/ Adam R. Brausa  
\_\_\_\_\_  
Signature